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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

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EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/870,009	Applicant(s) KASHIMA ET AL.	
	Examiner MICHAEL BURKHART	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/3/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8-12,15,17,18,20-27 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8-12,15,17, 18, 20-27 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt and entry of the amendment dated 12/3/2008 is acknowledged. After entry of the amendment, claims 5, 8-12, 15, 17, 18, 20-27, 30-35 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claims.**

The term "safely embedded" in claim 35 is a relative term which renders the claim indefinite. The term "safely embedded" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It cannot be determined what and what not is to be considered "safely embedded" in regards to the nucleotide sequences recited in the claim.

Claim Rejections - 35 USC § 102

Claims 5, 8-12, 15, 17, 18, 20-27 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendez et al (Nat. Genet., 1997) as evidenced by Albertson et al (1990) and the

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pYAC4 GenBank entry (1995). **This rejection is maintained for reasons made of record in the Office Action dated 9/3/2008, and for reasons set forth below. Claim 35 has been added due to amendments of the claims.**

Regarding new claim 35, the specification provides no definition of "safely embedded", hence the term is broadly interpreted to include any DNA sequence inserted into another wherein the resultant DNA can replicate. Since the transgenic mice of Mendez et al obviously survived, the chromosomes of said mice could obviously replicate, thus, the inserted DNA sequences are considered to be "safely embedded."

Response to Arguments

Applicant's arguments filed 12/3/2008 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Mendez et al do not teach that a number of embedded nucleotide sequences is greater than an appearance frequency of said sequences found naturally in the organism; 2) the embedded sequences can be used to identify the source of the genetic information; 3) the claimed methods can be used to detect illegal copying by a third party, a feature not taught by Mendez et al; 4) the watermark sequences alleged by the Examiner to be taught by Mendez et al are not found in a portion "other than a gene portion" as required by the claims; 5) Mendez et al do not teach correlation of the watermark with the source of the value-added gene; 6) Mendez et al do not teach the claimed molecule comprising a plurality of sequences embedded in a DNA molecule of an organism that is greater than the number of such sequences found naturally in the organism.

Regarding 1), 2) and 6), the yeast YAC sequences used by Mendez et al do not naturally occur in mice. See the detection of such sequences (or the lack of detection in unmodified

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mouse cells) by Mendez et al in Fig. 2. Thus, the number of such sequences in the modified transgenic mice is greater than the number found in the unmodified mice.

Regarding 3), this is an intended use, and is not recited in the claim. Furthermore, the skilled artisan could use the information known about the YACs used by Mendez et al to determine if a mouse had been "copied." That is, normal or unmodified laboratory mice do not have yeast YAC sequences, let alone the specific ones used by Mendez et al.

Regarding 4) and 6), it has been explained that the nucleotide sequences of Mendez et al are not found in a "gene portion" as set forth in the specification, e.g. Fig. 1 details that any sequence outside the exons and introns of a gene are considered a "portion other than a gene portion." The YACs used by Mendez et al comprised a number of such sequences, e.g. the ARS1, CEN4, and Tetrahymena telomeric sequences that do not code for any protein. Thus, by the definition set forth in the instant specification, they are a "portion other than a gene portion." The fact that the mice of Mendez et al expressed human antibodies is irrelevant: the "gene portions" encoding the antibodies were not used to teach any limitations of the instant claims. Furthermore, according to the claim language, any DNA sequence outside of the coding sequence of the value-added gene can be considered "a portion which is other than said gene portion." As set forth previously, this would include at the least, the various selection genes found in the YACs of Mendez et al because they lie outside of the "gene portion" of the "value-added" gene.

Regarding 5), this feature is taught by Mendez et al for reasons of record, see the detection of the yeast YAC sequences in murine cells as set forth above (Fig. 2). The detection of such sequences in cells which do not naturally comprise such yeast sequences is considered to

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be correlating these YAC sequences with their source, i.e. the YAC. Furthermore, these are not method claims, but rather they are product claims. It is thus unclear what structural limitation "is correlated with" places on such products. It appears to be an intended use limitation. The skilled artisan could have correlated the yeast YAC sequences with their source for reasons set forth above.

Claim Rejections - 35 USC § 101

Claims 5, 8-12, 15, 17, 18, 20-27 and 30-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. **This rejection is maintained for reasons set forth in the Examiners Answer dated 9/8/2006, the BPAI Decision dated 10/29/2007 (Appeal 2007-1627), and the Office Action dated 9/3/2008.**

Regarding new claim 35, see the explanation above for interpretation of "safely embedded." Cells infected with HIV can replicate, thus the replicate their DNA and any HIV genomes embedded therein. Because of this DNA replication, this is considered "safely embedded."

Response to Arguments

Applicant's arguments filed 12/3/2008 have been fully considered but they are not persuasive. Applicants essentially assert that the claims have been amended to recite that a number of the embedded nucleotides in the plurality of nucleotide sequences is greater than an appearance frequency of said nucleotide sequences that occur naturally in said organism.

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Such is not convincing. HIV does not occur naturally in humans, thus, the LTRs (a plurality of embedded nucleotide sequences) found in the chromosome of infected cells is a greater number than the frequency of such LTRs in an uninfected cell.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhardt/

Primary Examiner, Art Unit 1633